

### REMARKS

#### Amendments to the Specification

Applicants have amended the specification at paragraph 46 to correct inadvertent typographical errors. The statement "when B is H and X is C=O, then X, together with A, does not form a carbamate amino protecting group" has been amended to read; "when B' is H and X' is C=O, then X', together with A', does not form a carbamate amino protecting group. The variables "B", "X" and "A" have been amended to read variables "B'", "X'", and "A'". Support for this amendment can be found in paragraph 9.

Applicants have also amended the specification at paragraph 90 to distinguish trade names from generic names of chemical compounds. Applicants have also amended paragraph 90 to delete reference to the compound PR 39, its chemical name and reference to [SEQ. ID NO: 1].

No new matter has been added.

#### Amendments to the Claims

Claims 3-31 were pending in the present application. Claims 3 and 5 are amended to fix typographical errors and to claim the subject matter which Applicants regard as the invention with greater clarity. Support for these amendments can be found throughout the specification including, for example, in paragraph 26.

Claims 21, 23 and 24 have been amended to claim the subject matter which Applicants regard as the invention with greater clarity. Support for the amendment to claim 21 can be found on page 79, lines 2-6. Support for the amendment to claims 23 and 24 can be found throughout the specification including, for example, on page 79, lines 28 through page 80, line 2.

Claims 25 and 26 have been amended to distinguish trade names from generic names of chemical compounds. Support for these amendments can be found throughout the specification including, for example, in originally filed claims 25 and 26.

None of the amendments introduces new matter.

**Sequence Listing**

The Office Action states that the application discloses at least one sequence disclosure and therefore fails to comply with the requirements set forth in 37 CFR 1.821 through 1.825.

Applicants have amended the application to remove the sequence listing, therefore obviating the need to comply with 37 CFR 1.821 through 1.825.

**Provisional Obviousness-Type Double Patenting Rejection**

Claims 3 and 4 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of United States Patent 6,794,490 and over claim 1 of co-pending United States patent application 09/738,742.

Applicants enclose terminal disclaimers which obviate these grounds of rejections.

**Rejections under 35 U.S.C. § 112, first paragraph**

Claims 3-12 and 17 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way to enable one of skill in the art to make and/or use the invention. In particular, the Office Action asserts that "the scope is unduly broad in view of the enabling disclosure." Office Action at 4. For the following reasons, Applicants respectfully traverse this ground of rejection.

***The Office Action fails to Establish a Prima Facie Case of Nonenablement***

The Office Action states, as a rationale for the enablement rejection, "that 'undue experimentation' would be required to determine which of the claimed compounds can exhibit antibacterial activity." Office Action at 4. After reciting the eight *Wands* factors, the Office Action attempts to support this rationale by citing five references which discuss antibiotics that are unrelated to applicants claimed compounds. Office Action at 4-5. The Office Action then asserts that:

These and other references disclose that there do exist compounds which exhibit antibacterial activity, and many of these inactive compounds are structurally analogous to compounds that are active. The key point is that the factors which give rise to activity or inactivity are unknown in the art; and certainly the specification has made no attempt to discuss such factors. Accordingly, the skilled microbiologist cannot predict antibacterial activity merely by viewing a structure.

\* \* \*

It remains the case that "undue experimentation" would be required to determine which of the claimed compounds can exhibit antibacterial activity.

#### Office Action at 6.

Assuming for the sake of argument that the above statements are true, these statements are irrelevant to whether or not the pending claims are enabled by Applicants' specification. That is, the enablement requirement does not require Applicants or skilled microbiologists to "predict antibacterial activity merely by viewing a structure." Rather, to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, Applicants' specification must describe how to make and use the claimed invention in such a way that one of ordinary skill in the art would understand how to make and use the claimed invention. *See* MPEP § 2164 (8<sup>th</sup> ed., Rev. May 2004). Thus, what is relevant to the question of enablement is Applicants' disclosure of how to make and use the claimed invention. Accordingly, the Office Action has not established a prima facie case of nonenablement with respect to the presently pending claims.

#### ***Applicants Have Satisfied the Enablement Requirement by Sufficiently Disclosing How to Make and Use the Claimed Invention***

Applicants' specification describes the synthesis of more than four hundred compounds. *See* Examples 1, 1a, 1b, 1c, 1d, 1e, 1f, 1g, 1h, 2, 3, 3a, 3b, 4, 5, 6, 7, 7a, 8, 8a, 9,

9a, 10, and 10a on pages 92-108. This disclosure is more than sufficient to teach one of ordinary skill in the art how to make the compounds of the claimed invention. Applicants' specification also provides *in vitro* antibacterial data for more than three hundred ninety compounds. As described in Example 11 on page 108:

Compounds according to Formula I were tested for antimicrobial activity against a panel of organisms according to standard procedures described by the National Committee for Clinical Laboratory Standards (NCCLS document M7-A5, Vol. 20, No. 2, 2000) except that all testing was performed at 37°C.

Thus, any additional testing to determine antibacterial activity would be routine, not undue. If anything, the references cited in the Office Action demonstrate that testing for antibacterial activity is routine in the art, not undue experimentation.

In addition, Applicants' specification describes and teaches *in vivo* testing of the claimed invention. Specifically, in Example 12, Applicants describe determining the antibacterial activity of Compound 70 in mice. Results of Applicants' antibacterial testing are provided in Table III.

Finally, Applicants' specification provides abundant guidance on using the claimed invention in pharmaceutical compositions and for the treatment of bacterial infections. *See e.g.* pages 72-81. Thus, for all of the foregoing reasons, the presently pending claims satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

#### **Rejections under 35 U.S.C. § 102**

Claims 3, 5, 6, and 10-12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Abbott (USP 4,537,717), hereafter Abbott.

#### **Compound 24 of Abbott**

The Office Action states that compound 24 of Abbott is encompassed by claim 3 of the pending application when substituent variables are as follows:

$R = N(B)(X)_m-A$ , wherein  $B$ =hydrogen;  $X = -CO-$ ;  $A$ =alkyl;

$R^1 = N(B')(X')_m-A'$ , wherein  $B'$ =hydrogen,  $m=1$ ,  $X'=CO$ ;  $A'$ =*t*-butoxy;

$R^2 = -CH_2-CO$ -aminophenyl.

Applicants have amended claim 3 to correct a typographical error. The statement "when  $B$  is  $H$  and  $X$  is  $C=O$ , then  $X$ , together with  $A$ , does not form a carbamate amino protecting group" has been amended to read; "when  $B'$  is  $H$  and  $X'$  is  $C=O$ , then  $X'$ , together with  $A'$ , does not form a carbamate amino protecting group." The variables " $B$ ", " $X$ " and " $A$ " have been amended to read variables " $B'$ ", " $X'$ ", and " $A'$ ".

Accordingly, compound 24 does not anticipate claim 3 of the pending application, because  $X'$ , together with  $A'$  form a carbamate amino protecting group, which is excluded from pending claim 3.

Compound 23 of Abbott

The Office Action states that compound 23 of Abbott is encompassed by claim 3 of the pending application when substituent variables are as follows:

$R = N(B)(X)_m-A$ , wherein  $B$ =hydrogen;  $X = -CO-$ ;  $A$ =alkyl;

$R^1 = N(B')(X')_m-A'$ , wherein  $B'$ =hydrogen,  $m=1$ ,  $X'=CO$ ;  $A'=C_{12}$ -alkyl;

$R^2 = -CH_2-CO$ -aminophenyl.

The Office Action states that ambiguity arises because of the definition of the term alkyl in the specification and that  $C_{12}$ -alkyl can be interpreted to be viewed as either  $C_{12}$ -unsubstituted alkyl or  $C_{11}$ -alkyl that is substituted with a methyl group. The Office Action also states that because of this ambiguity, the exclusion of unsubstituted- $C_1$ - $C_{18}$ -alkyl in claim 3 is not effective to exclude  $C_{12}$ .

Applicants have amended claim 3 to define the term alkyl more clearly. As amended, claim 3 excludes an alkyl group substituted with another alkyl group.

Accordingly, for all of the foregoing reasons, applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b).

**Trademarks**

The Office Action suggests that trademarks should be capitalized in claims 25 and 26. Applicants have amended claims 25 and 26 to capitalize the trademarks ZIRACIN and SYNERCID. Applicants respectfully assert that all other chemical terms in claims 25 and 26 are generic names. Applicants have amended claims 25 and 26 so that all generic names are recited without capitalization.

**Rejoinder**

On page 2 of the Office Action dated August 24, 2004, it states "In the event that either of Groups 1 or 2 is elected, claims 13-16 will be rejoined with that group." Applicants requested rejoinder of claims 13-16 in the Response dated September 24, 2004. The claims have not been rejoined. Applicants respectfully request that claims 13-16 be rejoined.

In the Response dated September 24, 2004 Applicants also requested rejoinder of claims 29 and 30, which were amended to exclude non elected subject matter and to depend from elected subject matter. The claims have not been rejoined. Applicants respectfully request that claims 29 and 30 be rejoined.

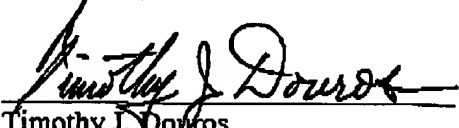
Applicants also request rejoinder of the corresponding methods of use and methods of synthesizing claims, claims 18-28 and claim 31, upon allowance of the pending claims.

CONCLUSION

For the reasons presented above, Applicants respectfully request reconsideration and prompt allowance of all pending claims. No additional fee is believed due in connection with the filing of this Amendment. However, the Commissioner is authorized to deduct any deficient amount or credit any surplus amount to Deposit Account No. 50-1986.

Respectfully submitted,

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